Recruitment script for INFECTIVITY CONTROLS (for e-mail, electronic, and telephonic use)

1. Study Objective: This study is being conducted to evaluate the safety and effectiveness of the adult and pediatric (child) formulations of an experimental malaria vaccine.

You are being asked to participate as an infectivity control. Infectivity controls **will not** be vaccinated, but will participate in the malaria challenge **only**. This is to prove that the mosquitoes are carrying the malaria parasites.

2. Study Duration: Infectivity controls will be enrolled in the study for approximately one month (28 days) from the day of challenge.

3. Number of People in the Study: Between 20 and 30 people will be enrolled as infectivity controls.

4. Study Background: Malaria is a parasitic disease transmitted by mosquitoes. It is a significant cause of death and disability in tropical areas of Africa, Asia, Oceania (Pacific islands) and Latin America. Humans become infected when they are bitten by infected mosquitoes. People don't feel well with this disease – its effects are similar to the flu, with symptoms such as fever, headache, body aches, upset stomach and diarrhea. Therefore, this disease impacts people and communities due to lost time in the home, at work and school.

A vaccine against the parasite would be a major contribution to public health. The U.S. Army is at the forefront of malaria vaccine research and development because soldiers are deployed to areas with malaria. In the current proposed study, we want to evaluate the effectiveness of a vaccine that has been under investigation here at the WRAIR CTC for several years.

5. Inclusion / Exclusion criteria:

To be eligible for this study you MUST:

- Be a male or non-pregnant, non-breastfeeding female (both civilian & military can enroll in this study)
- Be between the ages of **18 and 55**
- Be in good health
- Have no plans to travel to a country with malaria throughout the study
- Be a low cardiac risk

You may NOT be in this study if you have:

- History of malaria **within the last 5 years** or have received an investigational malaria vaccine Taken medication to prevent malaria within the past 60 days
- Heart, lung, liver, or kidney disease (high blood pressure, diabetes)
- Neurologic disease
- Had your spleen removed
- History of sickle cell disease or other blood diseases
- Positive for HIV or viral hepatitis
- Use of investigational drug or non-registered vaccine within 30 days before the first immunization
- Use of any vaccine within 7 days before the first immunization
- Allergic reaction to a vaccine
- Pregnancy or planned pregnancy during the study time period
- Use of certain prescription medications
- Inability to make all follow-up appointments
- Active duty military volunteers will require approval from their supervisory chain
- Alcohol or drug abuse

- Any other significant finding that in the opinion of the clinical investigators would make participation in the study unsafe

6. Study Plan:

Screening

A person who wants to enroll in the study will be screened to ensure they are eligible to participate. Screening includes:

- A detailed explanation of the study
- Completion of the informed consent documents
- Brief medical history and physical exam
- Urine pregnancy test and blood tests
- EKG (electrocardiogram which measures the "electrical activity" of the heart)

Challenge

- Volunteers will consent to participate in a malaria challenge to find out if the vaccine was effective. The challenge involves being bitten by mosquitoes infected with the malaria parasite. The mosquitoes are contained in a small cup with a screen on top. This procedure doesn't hurt, but the volunteer's arm may itch later, as with any mosquito bite. Volunteers will develop malaria from the mosquito bite.
- A urine pregnancy test will be performed for all women before the challenge

Post-challenge and Hotel Phase

- Volunteers will need to return to the Clinical Trials Center days 5-9 after the challenge to provide blood for testing.
- Starting the night of the 9th day after the initiation of malaria challenges, volunteers will need to check in to a local hotel for a maximum of 10 days to allow for rapid assessment and treatment by study staff. The reason is that this is the period of time volunteers are most likely to develop malaria.
    - Each morning, volunteers will be seen by a study physician and have a small amount of blood drawn to test for malaria.
    - Each afternoon, volunteers will speak with a staff member to get test results and report how they feel.
    - Volunteers will only have to sleep at the hotel, but can come and go for work and outside activities as long as they return for clinical visits.
- The symptoms of malaria include fever, chills, headache, fatigue, vomiting, diarrhea, muscle aches, and stomachache.
- When malaria does develop, volunteers will be treated with a medication taken by mouth, Chloroquine, which is taken 4 times within 48 hours. This drug is FDA approved and has been used safely for many years. The medication is expected to completely cure the malaria. We have other medications, Malarone® and Coartem®, for volunteers who may need an alternative to Chloroquine. Each of these medications can be completed within 2 -3 days.

Post-Hotel Phase

- All control (unvaccinated) volunteers will have their final visit approximately 1 month after challenge.
- Blood will be drawn at this visit.

7. Risks to the Volunteers may include:

- Note: study staff have methods to decrease or limit most, if not all, side effects
- From challenge: local reaction at the site where mosquitoes bite, side effects from the FDA-approved anti-malaria medication (such as upset stomach, nausea, diarrhea, tiredness, ringing in ears)
- From malaria: fever, chills, headache, fatigue, vomiting, diarrhea, muscle aches, and stomachache
- From blood draws: bruising at the site
- Loss of confidentiality: For each volunteer that participates in this study, there is a chance that limited volunteer information may be disclosed to persons outside of this study to include: representatives of GSK, the USAMRMC, the Food and Drug Administration (FDA), and the WRAIR Institutional Review Board (IRB). These representatives may have access to review research records as part of their responsibility to protect humans in research but they must also maintain confidentiality of volunteer records within the limits of the law.

8. Compensation: Volunteers will be paid for their participation in this study. Please refer to study schedule for payment details.

9. Study Setting: Outpatient clinic on a military base. You MUST have a valid state or government-issued photo ID & be able to pass a background check in order to gain access onto the base & participate in a study with us.

For more information on this study or to schedule a screening appointment, please call or email the WRAIR CTC using the contact information below and provide the following information to the staff:

1. Name
2. Date of Birth
3. Gender – M or F
4. Phone number
5. Email address
6. How you heard about this study

The above information will be entered into our secure database and is not shared with outside sources.

WRAIR Clinical Trials Center
503 Robert Grant Ave, Silver Spring, MD 20910
Hours: Mon-Fri, 6:00am – 2:30pm
Phone: 1-866-856-3259
Email: usarmy.detrick.medcom-wrair.mbx.clinical-trials@mail.mil